

REQUIREMENTS AND INSTRUCTIONS FOR FILING - WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Visit our website at: www.state.hi.us/dcca/pvl

ACTIVITIES COVERED UNDER THIS LICENSE

- Handling, distributing, or storing of legend or prescription pharmaceuticals, controlled substances, medical gases, transfilling of medical gases, or supplies and devices that contain or are accompanied by legend/prescription drugs, to persons other than a consumer or patient.

• "Wholesale distributor" means any person or entity in this State engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs. For purposes of this section, "manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug; and "prescription drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

APPLICATION IS REQUIRED WHEN

- A person or entity will be operating, maintaining, opening, storing, changing location, or establishing a wholesale prescription drug distribution within the State of Hawaii.
- Ownership changes.
- A person or entity will be operating, maintaining, opening, storing, or establishing a vendor-managed inventory arrangement ("consignment arrangement") within Hawaii.

Note: If the person or entity is licensed in its state of domicile, and does not have a facility, office, or vendor-managed inventory located in Hawaii, the person/entity is not required to obtain a wholesale drug distributor license.

CONTROLLED SUBSTANCES

Be advised that the State may have different substances listed in its schedules of controlled substances. You are required to register with the Department of Public Safety, Narcotics Enforcement Division, if you will be shipping controlled substances. For further information, contact:

Department of Public Safety
Narcotics Enforcement Division
Pacific Park Plaza
711 Kapiolani Blvd., Ste 1422
Honolulu, HI 96813
Phone: (808) 594-0150

APPLICATION FORM

COMPLETE IN DUPLICATE AND SUBMIT BOTH COPIES TO THE BOARD. Type or print legibly in dark ink.

MAP OF FACILITY

Attach two (2) copies of a map of the facility showing the storage area for drugs, the storage area for quarantined drugs, and the placement of the lighting, ventilation, and temperature control equipment. Schematic drawing will be accepted; need not be a blueprint nor to scale.

WRITTEN POLICIES AND PROCEDURES

Attach two (2) copies of written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs (which shall include medical gases) including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. These written policies and procedures shall include a procedure:

- 1) For the receipt, security, storage, inventory and distribution of prescription drugs;
- 2) For identifying, recording, and reporting losses or thefts and correcting errors in inventories;

WRITTEN POLICIES AND PROCEDURES (Cont.)

- 3) Whereby the oldest stock is distributed first;
- 4) For handling recalls and withdrawals of prescription drugs;
- 5) For handling return of outdated prescription drugs, its segregation and documentation of disposal; and
- 6) To ensure the handling of any crisis in the event of natural disasters or local, state, or national emergencies.

NEW LICENSE-BUSINESS FORMERLY OWNED BY SOMEONE ELSE

Attach a letter of verification from the former owner that the business (facility) has been bought and the effective date.

CORPORATION/ PARTNERSHIP/LLP

If the application is for a corporation, partnership, LLC, or LLP, submit the following proof to show that the entity is properly registered with the Business Registration Division (BREG), Department of Commerce & Consumer Affairs, State of Hawaii, P.O. Box 40, Honolulu, HI 96810.

If the corporation/partnership/LLC/LLP has been registered in this state for LESS THAN ONE (1) YEAR, ATTACH a "*filed-stamped*" copy of the document filed with BREG; or the same certificate mentioned below (copy acceptable).

If the corporation/partnership/LLC/LLP has been registered in this state for MORE THAN ONE (1) year, ATTACH a "*Certificate of Good Standing*" or "*Certificate of Qualification*" (copy acceptable).

VERIFICATION OF WORK EXPERIENCE

Submit written verification from a third party (for example, letter from a former employer) to verify the work experience of the person(s) who will be responsible for the distribution and handling of prescription drugs.

INSPECTION REQUIRED

An inspection conducted by the Department of Health, Food and Drug Branch, on the minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drugs distribution records shall be successfully completed before a license is issued. A copy of the inspection report is attached indicating the items for which the applicant will be inspected. Any item deemed unsatisfactory by the Department of Health shall prevent the issuance of a license. We will forward a copy of your application to the Department of Health.

FEES

A license will be issued upon fulfillment of the above requirements, passing an inspection of the facility, approval by the board and the receipt of the appropriate *fees due*.

Make check payable to *COMMERCE & CONSUMER AFFAIRS for the applicable fees*:

If applying for license in an EVEN-NUMBERED year, pay \$295
(Application fee-\$100, License-\$50, 1/2 renewal-\$75, Compliance Resolution Fund-\$70).

If applying for license in an ODD-NUMBERED year, pay \$185*
(Application fee-\$100, License-\$50, Compliance Resolution Fund-\$35).

If applying for Relocation, pay \$100
(Application fee-\$100-license fee not required).

**ALL licenses expire on December 31, ODD-NUMBERED years and are subject to renewal regardless of license issuance date.*

Note: One of the numerous legal requirements that you must meet in order for your new license to issue is the payment of fees as set forth in this application. You may be sent a license certificate before the check you sent us for your required fees clears your bank. If your check is returned to us unpaid, you will have failed to pay the required licensing fee and your license will not be valid, and you **may not** do business under that license. Also, a \$15.00 service fee will be charged for checks which are returned by the bank.

FEES (Cont.)

If for any reason you are denied the license you are applying for, you may be entitled to a hearing as provided by Title 16, Chapter 201, Hawaii Administrative Rules, and/or Chapter 91, Hawaii Revised Statutes. Your written request for a hearing must be directed to the agency that denied your application, and must be made within 60 days of notification that your application for a license has been denied.

ADDRESS OF BOARD

Mail all required items to:

Deliver to office location at:

*Board of Pharmacy
DCCA, PVL Licensing Branch
P.O. Box 3469
Honolulu, HI 96801*

or

*1010 Richards St., 1st Floor
Honolulu, HI 96813*

Phone: (808) 586-3000

Toll free voice access numbers for the neighbor islands:

Kauai - 274-3141 Ext. 6-3000
Maui - 984-2400 Ext. 6-3000
Hawaii - 974-4000 Ext. 6-3000
Molokai - 1-800-468-4644 Ext. 6-3000
Lanai - 1-800-468-4644 Ext. 6-3000

**LAWS & RULES
PUBLICATIONS**

Copies are available for purchase at the Cashier's Office, 3rd Floor, Department of Commerce & Consumer Affairs, 1010 Richards Street, P.O. Box 541, Honolulu, HI 96809. Make check or money payable to "Commerce & Consumer Affairs" in the amount of \$4.75. (Prices subject to change without notice).

1. Chapter 461, Hawaii Revised Statutes; Pharmacists & Pharmacies \$.50
2. Title 16, Chapter 95, Hawaii Administrative Rules, Pharmacists & Pharmacies \$1.25
3. Chapter 329, HRS, Uniform Controlled Substances Act \$1.25
4. Chapter 328, HRS, Food, Drugs and Cosmetics..... \$1.25
5. Chapter 436B, HRS, Professional and Vocational Licensing Law..... \$.50

**APPLICATION
STATUS**

It is the responsibility of the applicant to arrange for submission of all required documentation for timely completion of the application. Applicants may contact the Department of Commerce & Consumer Affairs periodically to monitor the status of their file with regard to receipt of supporting documents.

You may write or call the Licensing Branch. We are unable to return out-of-state calls.

Visit our website at: **www.state.hi.us/dcca/pvl**

This material can be made available for individuals with special needs. Please call the Licensing Branch Manager at (808) 586-3000 to submit your request.

APPLICATION FOR LICENSE - WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Date Routed to Department of Health

Applicant (Name of corporation, partnership or LLP; if individual, First, Middle, Last):

Effective Date

License No.

Trade Name (if used):

Location (include suite no., city, state & zip code):

Mailing Address (if different from location):

Website Address:

E-Mail Address:

Social Security No.

Business Phone No.

Toll free No. (if any)

Fax No.

FOR OFFICE USE ONLY

Check the type of application being made:

☐ NEW LICENSE. Business NOT owned by anyone else before.

☐ NEW LICENSE. Business formerly owned by someone else.
(Attach letter of sale).

Name of former owner & trade name:

dba _____

License number of former owner: _____

☐ RELOCATION. Same owner but in a different location.

Former location: _____

Is the premises ready for inspection? YES NO

If no, when will it be ready? _____

Circle type of business entity:

SOLE OWNER

LIMITED LIABILITY PARTNERSHIP

CORPORATION

PARTNERSHIP

If applicant is a corporation, partnership or LLP is verification attached to attest that the entity is properly registered with the Business Registration Division (BREG), Department of Commerce and Consumer Affairs, State of Hawaii?

Check one:

☐ Certificate of Good Standing (If registered more than one year)

☐ "Filed-stamped" copy of the document filed with BREG

Name and Position of person or persons responsible for the distribution of drugs, and an outline of at least one year's experience in the handling, storage, manufacture, or distribution of prescription drugs. Attach written verification from third-party. (If additional space is required, attach a separate sheet)

Have any of the applicants and/or persons responsible for the distribution of drugs had any:

1) Convictions relating to the distribution of drugs (including samples) YES _____ NO _____

2) Felony convictions YES _____ NO _____

3) Suspensions or revocations of licensure for the manufacture or distribution of drugs by federal, state, or local laws, of any license currently or previously held by the applicant or persons responsible for the distribution of drugs in any state the applicant is conducting business YES _____ NO _____

List, explain, and attach copies of court documents or the board's documents relating to these matters.

List all Parent or Subsidiary companies, if any:

App 496 \$100
Lic 499 \$ 50
CRF C13 \$35/70
½ Ren 490 \$ 75
Service Fee BCF \$ 15

RESIDENCE ADDRESSES	Name	Social Security No.	Residence Address	Phone No.
	Sole Owner			
	President, Partner, or Director			
	Vice-President, Partner, or Director			
	Secretary, Partner, or Director			
	Treasurer, Partner, or Director			

Business Entities Applicant will serve:

Type of Products to be handled and distributed by applicant:

- ☐ Pharmacies
- ☐ Practitioners
- ☐ Hospitals
- ☐ Wholesale/Distributors
- ☐ Other (list)

- ☐ Legend pharmaceuticals, supplies or devices
- ☐ Controlled substances
- ☐ Medical gases only

Are the written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs including procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories attached? ☐ Yes ☐ No

If no, give a date when it will be available: _____

(Note: An inspection with the Department of Health will not be scheduled until this and all other requirements are met.)

Affidavit of Applicant:

I solemnly swear that the answers and statements contained in this application and the documents attached are true and correct. I understand that misrepresentation is grounds for refusal or subsequent revocation of license (*Section 710-1017, Hawaii Revised Statutes*).

Further, I agree that the wholesale prescription drug distributor for which the license is sought is or will be in full compliance with all state drug, narcotic and poison laws, and Chapters 461 and 95, Hawaii Revised Statutes.

Date

Signature of Applicant

Print Name

Title _____

WHOLESALE DRUG DISTRIBUTOR INSPECTION FORM

FACILITIES:	S	U
A. Facility's size and construction facilitates cleaning, maintenance and proper storage.		
B. Storage areas provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions.		
C. Quarantine area maintained for storage of outdated, damaged, deteriorated, misbranded, adulterated prescription drugs.		
D. Facility is free from infestation from insects, rodents, birds and vermin of any kind.		
SECURITY:		
A. Facility is secured from unauthorized entry; only authorized personnel are allowed into prescription drug area.		
B. Access from outside premises is kept to a minimum.		
C. Outside perimeter is well lighted.		
D. Facility is equipped with alarm system.		
E. Facility is equipped with security system to provide protection from theft and diversion.		
STORAGE:		
A. Prescription drugs stored at appropriate temperature and conditions as defined in an official compendium.		
B. Firm is equipped with appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, logs.		
RETURNED OR DAMAGED DRUGS:		
A. Damaged, outdated, deteriorated, misbranded or adulterated drugs are physically separated from other prescription drugs.		
EXAMINATION OF MATERIALS:		
A. All outgoing and incoming merchandise is examined for damage and accuracy.		
RECORD KEEPING: Records kept at the firm indicate the following:		
A. Source of drugs, name and principal address of seller or transferor, and address from which drugs were shipped.		
B. Identify and quantity of drugs received and distributed/disposed, date of receipt and distribution/disposal.		
C. Records are stored at the firm or are easily retrievable by computer. Records are stored for five years.		
RESPONSIBLE PERSONS:		
A. Current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm.		
B. Description of duties and qualifications of personnel is maintained at the firm.		
SALVATION AND REPROCESSING:		
A. Salvaging and reprocessing operation in compliance with 21 CFR 207, 210, 211.		
WRITTEN POLICIES AND PROCEDURES:		
A. Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs.		
B. Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories.		
C. Firm has a procedure where oldest stock is distributed first.		
D. Firm has a procedure for handling recalls/withdrawals of prescription drugs.		
E. Firm has a procedure for handling return of outdated prescription drugs; segregation and written documentation of disposal.		
F. Procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or emergencies.		
COMMENTS:		